

Appl. No. 10/798,460
Atty. Docket No. CM 2731
Amdt. dated April 3, 2007
Reply to Office Action of Jan. 3, 2007
Customer No. 27752

REMARKS

Claim Status

Claims 1-5 and 7-18 are pending in the present application.

Claims 1 and 12 have been amended to delete the unneeded brackets.

These changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested. No additional claims fee is believed to be due.

Claim Objections

The Office objected to Claims 1 and 12 because of the unnecessary brackets. Claims 1 and 12 have been amended to remove the brackets.

Rejection Under 35 USC §112, Second Paragraph

The Office Action states that the range covered "by 'greater than about 10' is unclear because the term 'about 10' itself covers the number which is greater or less than 10. The phrase denotes a limitation within a limitation, and the metes and bounds of the scope of the limitation is unclear." Applicant respectfully disagrees with the Office's argument. According to the Office's reasoning, the use of the term "about X" is unclear since the term covers values greater or less than X. Such reasoning would result in any use of the term "about" as being unclear. It is well established that "about" should be given the ordinary and accepted meaning of "approximately." *Merck & Co. v. Teva Pharmaceuticals USA Inc.*, 73 U.S.P.Q.2d 1641, 1648 (Fed. Cir. 2005). Applicant requests withdrawal of the rejection.

Rejection Under 35 USC §103(a)

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings. See *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992); MPEP § 2143.01. Second, there must be a reasonable expectation of success for

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the proposed modification. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); MPEP § 2143.02. Third, the prior art reference or combined references must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981 (CCPA 1974); MPEP §2143.03. Furthermore, in establishing a *prima facie* case of obviousness, case law clearly places the "burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103." *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967).

Claims 1-5, 7-15, and 17-18 have been rejected under 35 USC §103(a) as being unpatentable over U.S. Publication 2002/0041889A1 to Masuda et al ("Masuda") in view of U.S. Patent No. 6,217,888 to Oblong et al. ("Oblong"). In support of this rejection, the Office argues that it would have been obvious to one of ordinary skill in the art at the time the present invention was made to modify the exemplified cosmetic compositions of Masuda by incorporating a vitamin B₃ of Oblong. Applicant traverses the rejection because the Office has failed to make a *prima facie* case of obviousness.

First, Masuda does not teach or suggest all of the claim limitations. The Office points to various exemplary preparations (e.g., Examples 3, 6, 8, 10, and 11) of Masuda. The Office acknowledges that Masuda "does not provide a specific motivation to select the vitamin B₃ compounds." The Office relies on Oblong as a supplementary reference directed to the vitamin B₃ compounds. The Office's rejection presumes that the only missing element in the Examples of Masuda is the vitamin B₃; however, several of the Examples relied upon by the Office fail to teach other elements required by the pending claims. Two such examples are as follows:

- The Office states, "Masuda et al. teach a topical preparation comprising 6% of 1,3-butylene glycol, 4% of glycerine, DL-serine, and N,N,N-trimethylglycine (a zwitterionic moisturizing factor). See Preparation Example 3." However, Masuda's Example 3 fails to teach the 7% of glycerine as required by independent Claims 1 and 17 or the about 10%-15% of glycerine as required by independent Claim 12.
- The Office states, "Example 8 teaches a cleansing foam comprising 10% of glycerine, which meets the glycerine weight limitation of instant claims 1(a), 12(a), and 18."

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However, Masuda's Example 8 fails to teach the zwitterionic moisturising factor comprising a quaternary ammonium salt as required by independent Claims 1 and 12. The specific Examples of Masuda fail to teach not only the limitation of a vitamin B₃ compound but also at least one of the other limitations present in the pending claims. The Office has presented no explanation addressing the missing elements in the Examples of Masuda. Therefore, a *prima facie* case of obviousness has not been met.

Claim 8 - The Office points to the disclosure within Oblong that a suitable emulsion may be a water-in-silicone emulsion. However, the Office has provided no motivation for modifying the exemplary formulations of Masuda, which do not appear to involve water-in-silicone emulsion. As a result, a *prima facie* case of obviousness has not been established.

Claims 9-11 - The Office points to Example 6 of Masuda for teaching the use of 0.2% of methylcellulose. However, Example 6 contains no glycerin, no vitamin B₃ compound, and no zwitterionic moisturising factor comprising a quaternary ammonium salt. The Office has provided no motivation for modifying any of the other examples in Masuda to include a thickening agent and, specifically, a thickening agent comprising a carbomer, a polyacrylamide, polyacrylates, a sodium acrylate copolymer, a polyacrylamide, isoparaffin, a laureth-7 co-polymer, or mixtures thereof.

Claims 12-14 - With respect to weight percentages of glycerine, the Office argues:

[T]here appears to be no criticality in modifying the weight amount of the glycol as required by the present claims. As discussed above, the reference teaches formulations which contain both 4% glycerine and 6% 1,3-butylene glycol, as well as a formulation which contains 10% of glycerine alone. Since glycerine and 1,3-butylene glycol are art recognized functional equivalents that are added or substituted in place of the other, it is viewed that a skilled artisan would have discovered an optimum weight amount of these glycols to render desired humectancy by routine experimentations.

Applicant respectfully refutes the Office's assertion. By stating that "glycerine and 1,3-butylene glycol . . . are added or substituted in place of the other," the Office is implying that the two compounds are interchangeable. One skilled in the art would recognize that

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this is not the case. Applicant respectfully requests the Office to consider the declaration of Ms. Alison Stephens submitted under 37 C.F.R. § 1.132 which accompanies the present correspondence. Ms. Stephens presents factors that must be considered when comparing glycerine and 1,3-butylene glycol. Specifically, Ms. Stephens points to the higher dielectric constant and hygroscopicity of glycerine which results in far superior moisturization compared to 1,3-butylene glycol. Therefore, one skilled in the art would recognize that glycerine and 1,3-butylene glycol may not simply be "added or substituted in place of the other." Furthermore, the specification evidences the inferiority of 1,3-butylene glycol by noting that it is "disadvantageous to use 1,3-butylene glycol." Page 4, line 1. The Office has not established a *prima facie* case of obviousness because the rationale for the modification is in error.

The Office states, "[T]here appears to be no criticality in modifying the weight amount of the glycol as required by the present claims." Applicant directs the Office to the paragraph beginning on page 3, line 4 of the instant application. Applicant states, "[I]t is believed that the high levels of glycerine herein are useful in combination with a vitamin B₃ compound and NMFs. It is believed that, central to the efficacy of this combination, is the concentration of glycerine, above 7%." The criticality of the weight percentage of glycerine is clearly presented.

The Office states, "a skilled artisan would have discovered an optimum weight amount of these glycols to render desired humectancy by routine experimentations." The Office's assertion of optimization by "routine experimentation" is based on an impermissible "obvious to try" standard. Case law describes a typical fact pattern where the impermissible "obvious to try" rationale is often used. "In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Masuda does not address the criticality of glycerine or 1,3-butylene glycol.

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In summary, the Office's argument regarding the interchangeability of glycerine and 1,3-butylene glycol is incorrect because one skilled in the art would recognize that glycerine and 1,3-butylene glycol may not simply "added or substituted in place of the other" as asserted by the Office, the Office failed appreciate glycerine function as recited in the application, and the Office uses an "obvious to try" rationale.

Claims 13-14 and 17 - Claims 13-14 and 17 require a composition having greater than 7% of glycerine and less than 7% of a humectant other than glycerine. Masuda provides no teaching or suggestion of a composition having greater than 7% of glycerine and less than 7% of a humectant other than glycerine. The Office states, "a skilled artisan would have discovered an optimum weight amount of these glycols to render desired humectancy by routine experimentations." The Office's assertion of optimization by "routine experimentation" is an impermissible "obvious to try" standard. Masuda does not address the criticality of the weight percent of glycerine or the weight percent of 1,3-butylene glycol. Masuda provides no direction as to the "optimum weight amount of these glycols to render desired humectancy."

Claims 16 is rejected under 35 USC §103(a) as being unpatentable over Masuda and Oblong in view of PCT Publication WO 92/19216 to Cooke et al. ("Cooke"). The Office states, "Masuda et al. and Oblong et al. do not specifically teach using glycerine to the weight amount as required by instant claim 16." However, the Office notes, "Cooke et al. teach an aqueous gel formulation for skin or hair care, which comprises 0.5-20 % by weight of glycerine, or 0.5-30 % by weight of a polyhydric alcohol humectant, along with the ingredients which form and stabilize the aqueous gel." Applicant traverses the rejection.

Cooke adds little to Masuda and Oblong. Specifically, Cooke states, "In the present compositions, glycerine is present at a level of from about 0.5% to about 20%." Page 3, lines 13-15. This is not greater than 25% of glycerine as recited in Claim 16. The Office point to a teaching of 0.5-30% by weight of a polyhydric alcohol humectant, but Cooke notes "[p]olyhydric alcohol humectants other than glycerol." When considering the disclosure as a whole, the 30% weight percent is for polyhydric alcohol humectants

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other than glycerine. Cooke fails to teach or suggest the limitation are recited in Claim 16.

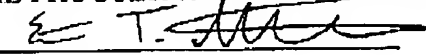
CONCLUSION

This response represents an earnest effort to place the application in proper form and to distinguish the invention from the applied references. In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under §§ 103(a) and 112. Reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-5 and 7-18 is respectfully requested.

Respectfully submitted,

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